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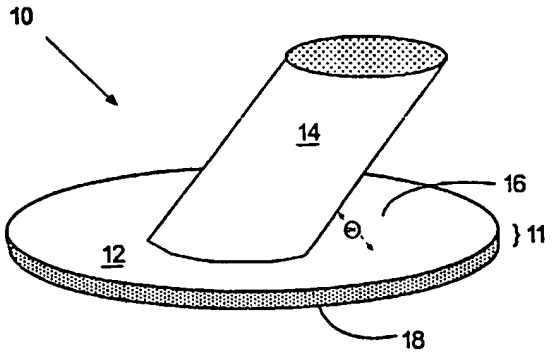
(54) Title: ANASTOMOSIS SYSTEM AND METHODS FOR USE



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(57) Abstract: An anastomosis system, and methods for its use in end to side anastomoses are provided. The subject anastomosis system includes nesting, first, and second structural means (10, 20) which are each tubular in structure, have a lip (12) at least at one end. In performing an end to side anastomosis according to the subject invention, the subject anastomosis system is used to stably attach the graft vessel to the side of the host vessel in a manner that provides for fluid communication between the lumens of the graft, and host vessels. Also provided are kits that include the subject systems. The subject anastomosis systems, and methods find use in a variety of different anastomosis applications, including vascular anastomoses, and particular proximal anastomoses.

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ANASTOMOSIS SYSTEM AND METHODS FOR USE

CROSS REFERENCE TO RELATED APPLICATIONS

Pursuant to 35 U.S.C. § 119 (e), this application claims priority to the filing date of the United States Provisional Patent Application Serial No. 60/136,707 filed May 28, 1999, the disclosure of which is herein incorporated by reference.

INTRODUCTION

Technical Field

The field of this invention is anastomosis, and more particularly end-to-side anastomosis.

Background of the Invention

Anastomosis is the union or connection of one tubular structure to another so that the interiors of the tubular structures communicate with one another. There are generally two types of anastomoses: end-to-end and end-to-side. In an end-to-end anastomosis, the ends of two different tubular structures are joined together. In an end-to-side anastomosis, however, the severed end of one tubular structure is connected around an opening cut into the side of a second tubular structure.

Anastomoses have been performed with a variety of different types of tubular structures or vessels in order to achieve a desired patient outcome. Typically, anastomoses are performed between airways, blood vessels, bowel segments, and urogenital tubes. The procedure for connecting blood vessels is referred to as vascular anastomosis.

One of the best known surgical procedures utilizing vascular anastomoses is the coronary bypass. In the context of coronary artery disease, the flow of oxygenated blood to the myocardium of the heart is impeded or compromised by a stenosis or obstruction in the coronary artery. This flow can be improved by providing a coronary

artery bypass graft ("CABG") which diverts blood flow around the stenosis, thereby restoring myocardial circulation. In these procedures, a graft (e.g. a saphenous vein graft, a LIMA graft or a synthetic graft) is harvested and attached to the aorta on one side of the stenosis utilizing an end-to-side proximal anastomosis and to a coronary artery on the other side of the stenosis utilizing an end-to-side distal anastomosis. In other words, a proximal end-to-side anastomosis and distal end-to-side anastomosis are performed, where the graft vessel is attached at the proximal site to the aorta and at the distal site to a coronary artery. In this specification, the terms proximal and distal are used according to their conventional meanings to those of skill in the art, where proximal refers to the end closest to the center/origin/source and distal refers to the end farthest away. As such, in terms of bypass procedures, proximal refers to the aorta or main/larger vessel while distal refers to the smaller, more distant graft vessel.

While a variety of different devices and methodologies have been developed over the years to perform anastomoses, including vascular anastomoses, there continues to be a need and an interest to develop new and better methods and devices for performing such procedures. Of particular interest would be the development of methods and devices that make end-to-side anastomoses simple and rapid to perform, thereby decreasing resource usage, e.g., operating room time, physician training, etc. With respect to vascular anastomosis devices, of particular interest would be the development of an anastomosis system that is capable of being used to perform a proximal end-to-side anastomosis, particularly while the heart is still beating and that establishes intima-to-intima contact of the two vessels being joined. Such improved methods and devices would lead to a number of advantages, including less expense, faster patient recovery, and the like.

Relevant Literature

Patents of interest include: 2,453,056; 4,366,819; 4,368,736; 4,470,415; 4,523,592; 5,695,504; 5,702,412; 5,797,934; and 5,817,113.

SUMMARY OF THE INVENTION

An anastomosis system and methods for its use in end-to-side anastomoses are provided. The subject anastomosis system includes nesting first and second structural means which are each tubular in structure and have a lip on at least one end. In

performing an end-to-side anastomosis according to the subject invention, the subject anastomosis system is used to stably attach the graft vessel to the side of the host vessel in a manner that provides for fluid communication between the lumens of the graft and host vessels. Also provided are kits that include the subject systems. The subject anastomosis systems and methods find use in a variety of different anastomosis applications, including vascular anastomoses and particularly proximal anastomoses.

BRIEF DESCRIPTION OF THE FIGURES

Fig. 1 provides a representation of a first structural means according to the subject invention.

Fig. 2 provides a representation of a second structural means according to the subject invention.

Figs. 3A and 3B depict two different embodiments of a graft vessel attached to the first and second structural means of an anastomosis system according to the subject invention.

Figs. 4A to 4D provide a step-by-step representation of the eversion of the distal end of a graft vessel over the distal surface of the lip of a first structural means in the process of producing a prepared graft vessel according to the subject invention.

Fig. 5 shows a prepared graft vessel according to the subject invention.

Fig. 6 provides a cross-sectional view of the site of attachment of the graft and host vessel following an end-to-side anastomosis according to the subject invention.

Fig. 7 provides a three-dimensional view of a rigid first structural means.

Fig. 8 provides a three-dimensional view of a rigid second structural means.

Figs 9 provides a three-dimensional view of the first and second structural means shown in Figs. 7 and 8, respectively, in a partially nested configuration.

Figs. 10A to 10C provide different views of a delivery device according to the subject invention.

Figs. 11A to 11N provide a sequential showing of the various steps of securing a graft vessel to the side of a host vessel using the methods and devices of the subject invention.

DESCRIPTION OF THE SPECIFIC EMBODIMENTS

Anastomosis systems and methods for their use in performing end-to-side anastomoses are provided. The subject systems include nesting first and second

structural means that have a tubular structure and a lip on at least one end. In practicing the subject methods, the anastomosis system is used to stably attach the graft to the host vessel in a manner such that fluid communication is established between the graft and host vessels. Also provided are kits for use in performing end-to-side anastomoses according to the subject invention. In further describing the subject invention, the anastomosis system and components thereof (e.g., first and second structural means) are described first, both generally and in terms of specific embodiments depicted in figures, followed by a discussion of the subject methods of performing end-to-side anastomoses and kits that include the subject anastomosis systems.

Before the subject invention is described further, it is to be understood that the invention is not limited to the particular embodiments of the invention described below, as variations of the particular embodiments may be made and still fall within the scope of the appended claims. It is also to be understood that the terminology employed is for the purpose of describing particular embodiments, and is not intended to be limiting. Instead, the scope of the present invention will be established by the appended claims.

In this specification and the appended claims, the singular forms "a," "an" and "the" include plural reference unless the context clearly dictates otherwise. Unless defined otherwise, all technical and scientific terms used herein have the same meaning as commonly understood to one of ordinary skill in the art to which this invention belongs.

ANASTOMOSIS SYSTEM

As summarized above, the subject invention provides an anastomosis system that enables one to stably attach the end of a graft vessel to the side of a host vessel in a manner such that fluid communication between the lumens of the graft and host vessels is established. The systems of the subject invention are made up of nesting first and second structural means. The first and second structural means share many common features. The first and second structural means have a tubular structure with a

lip at one end. The lip of each structural means in certain embodiments is characterized by expanding radially outward in substantially all, if not all, directions from the base of the tubular region of the structural means. The shape of the lip may have any convenient shape configuration, including square, rectangular and curvilinear shape, such as oval, circular, irregular etc., where in many embodiments, the lip has a curvilinear configuration. i.e., the perimeter of the lip is curvlinear in shape.

A feature of the first and second structural means of the subject systems is that the first and second structural means are nesting, by which is meant that the tubular region of one of the structural means (typically the first structural means) fits inside the tubular region of the other structural means (typically the second structural means). In other words, the two structural means can be fit together in a manner such that the tubular member of one of the structural means can be positioned inside the tubular member of the other structural means. As such, the first and second structural means of the subject systems are capable of assuming a nested configuration. As the first and second structural means are capable of assuming a nested configuration, the outer diameter of one of the structural means is necessarily shorter than the inner diameter of the other structural means, e.g., the outer diameter of the first structural means is shorter than the inner diameter of the second structural means. The difference in diameters should be large enough to provide for insertion of one of the tubular members into the other tubular member but small enough to provide for a substantially snug fit when positioned in an end-to-side anastomosis.

The structural means may be made up of rigid materials, flexible materials, or be a composite of both rigid and flexible materials. Whether the materials are flexible or rigid, they should be biocompatible in view of the use of the subject structural means. By biocompatible is meant that they should be capable of being implanted and maintained in an animal host for a substantial period of time with little or no, and preferably no, toxic effects for the animal host. Examples of suitable rigid biocompatible materials include, but are not limited to: medical grade alloys, such as cobalt-chromium alloy, titanium alloy, stainless steel, ceramics and composite materials, and the like. Examples of flexible materials include elastic materials, where suitable elastic materials are materials that exhibit elasticity at a relevant temperature range, i.e., below room temperature to body temperature, e.g., from about 10 to 50 °C

at least, and are biocompatible. One type of biocompatible elastic material of interest is the class of memory alloys, including those described in: 5,876,434; 5,797,920; 5,782,896; 5,763,979; 5,562,641; 5,459,544; 5,415,660; 5,092,781; 4,984,581; the disclosures of which are herein incorporated by reference, e.g., biocompatible alloys that find use include those nickle-titanium (NiTi) shape memory alloys sold under the Nitinol™.

Whether or not the first and second structural means are fabricated from rigid or flexible materials, the first and/or second structural means may be modified in a number of different ways so as to alter the properties of the materials from which they are fabricated, e.g., the surface properties of one or more of the elements. As such, in many embodiments, one or more components of the structural means may be coated with a biocompatible polymeric membrane coating. The membrane coating may be fabricated from any convenient biocompatible polymer, where suitable biocompatible polymers include, but are not necessarily limited to: biocompatible polymers and/or elastomers. Suitable biocompatible polymers include, but are not necessarily limited to, materials such as, for example, polyethylene, homopolymers and copolymers of vinyl acetate such as ethylene vinyl acetate copolymer, polyvinylchlorides, homopolymers and copolymers of acrylates such as polymethylmethacrylate, polyethylmethacrylate, polymethacrylate, ethylene glycol dimethacrylate, ethylene dimethacrylate and hydroxymethyl methacrylate, polyurethanes, polyvinylpyrrolidone, 2-pyrrolidone, polyacrylonitrile butadiene, polycarbonates, polyamides, fluoropolymers such as polytetrafluoroethylene and polyvinyl fluoride, polystyrenes, homopolymers and copolymers of styrene acrylonitrile, cellulose acetate, homopolymers and copolymers of acrylonitrile butadiene styrene, polyvinylchloride, silicone rubber, polymethylpentene, polysulfones, polyesters, polyimides, polyisobutylene, polymethylstyrene and other similar compounds known to those skilled in the art. Suitable, biocompatible elastomers include, but are not necessarily limited to, biocompatible elastomers such as medical grade silicone rubbers, polyvinyl chloride elastomers, polyolefin homopolymeric and copolymeric elastomers, urethane-based elastomers, and natural rubber or other synthetic rubbers, fluorinated polymers (*e.g.*, PTFE), and the like. It should be understood that these possible biocompatible materials are included above for exemplary purposes and should not be

construed as limiting.

In certain embodiments, the biocompatible polymer may have one or more active agents or drug compounds associated with it, such that the structural means also serve as a drug delivery means, e.g., a slow release drug delivery means. A variety of different active agents may be delivered using the structural means of the subject invention, where such active agents include small organic molecules, either synthetic or naturally occurring; peptides; proteins; nucleic acids; etc. Active agents of interest include: agents having anti-restinosis activity, such as those disclosed in U.S. Patent Nos. 5,492,926; 5,462,937; 5,457,113; 5,599,227; 5,569,647; 5,428.151; active agents having anti-cell proliferation activity, active agents having anti-thrombotic activity; as well as other agents that may be desirable; and the like.

Despite the above common features of the first and second structural means of the subject invention, differences between the first and second structural means do exist. Accordingly, each of the first and second structural means is now described in greater detail separately below.

First Structural Means

As described above, the first structural means is a tubular structure that is flared at one end to form a "lip" feature extending beyond the outer diameter of the tubular region. Fig. 1 provides a three-dimensional view of a first structural means according to the subject invention. where the first structural means is a simple configuration made up of an elongated tubular member that is flared at one end to form a lip. As can be seen in Fig. 1, the first structural means 10 has an elongated tubular region or member 14 with a flared end or lip 12 at one terminus. Lip 12 has an upper surface 16 and a lower surface 18.

The lip 12 has an area that is sufficiently large to provide for stable attachment of the graft vessel to the side of the host vessel following an anastomosis procedure, as described in greater detail below. In other words. the lip has an area that is sufficiently large such that it provides for stable attachment of the graft to the host vessel and cannot be readily pulled out of the opening in the side of the host vessel into which it has been inserted in the subject methods. The area of the lip (defined by the outer

perimeter of the lip and including the area of the empty space or opening located where the tubular end expands into the lip) may vary considerably depending on the nature of the two vessels to be joined. For example, where the anastomosis system is designed to be used in a vascular end-to-side anastomosis, particularly a proximal end-to-side anastomosis of a graft vessel to the aorta, the area of the lip is at least about 5 mm^2, usually at least about 10 mm^2 and more usually at least about 20 to 30 $mm^2$and in some embodiments at least about 35 mm^2. The area of the lip typically does not exceed about 60 mm^2 and usually does not exceed about 40 mm^2.

As mentioned above, the shape of the flared end or lip of the first structural means may be any convenient shape, e.g., square, rectangular, triangular, trapezoid, circular, oval etc., but is generally a curvilinear shape, where any convenient curvilinear shape may be employed, such as: circular, oval, or other convenient curvilinear shape, including an irregular curvilinear shape, a curvilinear shape with scalloped edges, etc. The lip should be as thin as possible such that fluid flow in the host vessel following anastomosis is not substantially impeded or compromised by the presence of the lip and graft tissue everted over it, as described in greater detail supra. As such, the thickness 11 typically ranges from about 0.005 to 1.0 mm, usually from about 0.01 to 0.5 mm and more usually from about 0.05 to 0.25 mm.

The length of the tubular member or element of the first structural means may vary greatly depending on the nature of the vessels to be joined, where the length is typically just long enough to provide the required support function at the site at which the graft vessel is attached to the host vessel. The tubular region of the structural means has a generally curvilinear, and usually substantially circular, cross-sectional shape extending its entire length. The inner diameter varies in length depending on the particular graft vessel for which the first structural means is designed to be used. For example, in vascular anastomoses, particularly proximal anastomoses in which a graft vessel as anastomosed to the side of the aorta, the inner diameter is generally at least about 2 mm, usually at least about 3 mm and more usually at least about 4 mm. The outer diameter of the structural means is chosen so as to fit inside the second structural means, described in greater detail *infra*, such that the tubular region of the first structural means is capable of nesting inside the tubular region of the second structural means, as described above. In many embodiments, the length of the first tubular means

ranges from about 1 to 25, usually from about 2 to 20 and more usually from about 2 to 15 mm.

In certain embodiments, the joint angle θ between the outer wall of the tubular region and the lip (See FIG. 1) is chosen so as to facilitate fluid flow from the host vessel into the graft vessel. Generally the joint angel θ is between about 30 and 75°, usually between about 40 and 60°, where in many embodiments the joint angle θ is about or is between about 45 and 60 °.

The first structural means may optionally comprise one or more locking means which prevents removal of the second structural means from the first structural means following attachment of the graft and host vessels, as described in greater detail *infra*. This locking means may take on a variety of different configurations, so long as it prevent separation of the first and second structural means following their placement into a nesting position during use, e.g., so long as it prevents unwanted backwards movement (i.e., movement away from the host vessel) of the second structural means relative to the first structural means. This locking means may be permanent or reversible, i.e., the locking means may be one-way or two-way. An example of a one-way locking means may be one or more spaced apart protrusions on the outer surface of the tubular region of the first structural means which act like "barbs" to provide for one-way movement of the second structural means onto the first structural means. Another example of a locking means may be ratchet means, e.g., as made up by tooth on one of the structural means and corresponding groove on the other of the structural means, that provides for the one-way movement, as described in greater detail below. Examples of two-way or reversible locking means include ratchet elements that can be locked and released, e.g., by turning one element relative to another, as describe in greater detail below. As such, the locking means may be a single element present on either the first or second structural means, or a combination of elements present on both the first and second structural means.

In certain embodiments, the first structural means may also include a mechanical engaging means for securing the first structural means to tissue, e.g., for securing the first structural means to the graft vessel. This engaging means may be in any convenient form, such as one or more, usually a plurality of, spikes extending upward from the proximal surface of the lip of the first structural means. The spikes

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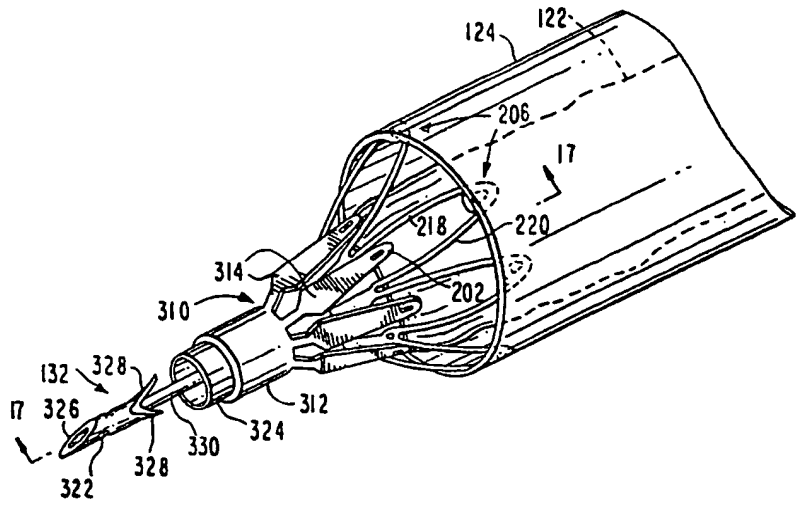
[Continued on next page]

(54) Title: SURGICAL GRAFTING APPARATUS AND METHODS



(57) Abstract: Instrumentation for facilitating cutting an opening in a side wall of a body conduit in a patient. A tubular structure defines a lumen and has a sharpened distal end portion configured to cut a section of the body conduit to create the opening. A tissue holding structure is provided which is axially movable within the lumen of the tubular structure. The tissue holding structure includes a piercing portion to permit passage of the tissue holding structure through the body conduit from an entrance side to an exit side thereof. The tissue holding structure also includes a retention member to secure the section of the body conduit to the tissue holding structure during movement of the tissue holding structure to approximate the entrance side of the body conduit with the sharpened distal portion of the tubular structure to enable the sharpened distal structure to cut the body conduit. A connector is also provided for attaching a new length of tubing to the body conduit at the opening made by the cutting.

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INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
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According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	DE 196 50 204 A (AESCULAP) 18 June 1998 (1998-06-18) figures 1,3,4	1,2,11
X Y	US 5 893 369 A (LEMOLE) 13 April 1999 (1999-04-13) column 7, line 61 - line 62; figures 5-8,12	1,2,11 3,10
Y	US 5 827 316 A (YOUNG) 27 October 1998 (1998-10-27) abstract	10
Y	US 5 470 320 A (TIEFENBRUN) 28 November 1995 (1995-11-28) column 5, paragraph 2; figure 4	3

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
10 January 2001	19. 01. 2001

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Barton, S

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Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Inte. onal Application No
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 5 690 662 A (CHIU) 25 November 1997 (1997-11-25) abstract	10
X	US 5 695 504 A (GIFFORD) 9 December 1997 (1997-12-09) figures 27,43-49	1,12
P,X	WO 99 38454 A (VASCULAR SCIENCE) 5 August 1999 (1999-08-05) figures 6,22,25,28	1,12,13
P,X	WO 00 27311 A (ST JUDE) 18 May 2000 (2000-05-18) figures 34-41	1,12,13
P,X	WO 00 27313 A (ST JUDE) 18 May 2000 (2000-05-18) figures 7-11,25	1,12,13

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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 00/15259

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 22-44
because they relate to subject matter not required to be searched by this Authority, namely:

Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

see additional sheet

1. [X] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[X] No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

1. Claims: 1-11

   Anastamosis punch with tissue securing barb

2. Claims: 1,12-21

   Anastamosis punch with anastomotic coupling

INTERNATIONAL SEARCH REPORT

Information on patent family members

Inte: ɔnal Application No
PCT/US 00/15259

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